B. Eligibility, Election, and Enrollment

1. Eligibility to Elect an M+C Plan (§422.50)

Section 1851(a) of the Act sets forth the criteria for an individual to be eligible to elect an M+C plan. Consistent with the statute, §422.50 specifies that an individual is eligible to elect an M+C plan if he or she:

- Is entitled to Medicare under Part A and enrolled in Part B (except that an individual entitled only to Part B and who was enrolled in an HMO or Competitive Medical Plan (CMP) with a risk contract under part 417 on December 31, 1998 may continue to be enrolled in the M+C organization as an M+C plan enrollee);
- Has not been medically determined to have end-stage renal disease, except that an individual who develops end-stage renal disease while enrolled in an M+C plan or other health plan offered by an M+C organization may continue to be enrolled in the M+C plan, or if enrolled in another health plan, may enroll in an M+C plan offered by the organization, if the individual is otherwise eligible to enroll in the M+C plan;
- Resides in the service area of the plan, except that an individual who resides in a continuation area of an M+C plan while enrolled in a health plan offered by the M+C organization may continue to be enrolled with the M+C organization as an M+C plan enrollee under the terms that apply to enrollees in the continuation area;

• Completes and signs an election form and gives information required for enrollment; and

• Agrees to abide by the rules of the M+C organization after they are disclosed to him or her in connection with the election process.

We specified in the interim final rule that an M+C-eligible individual may not be enrolled in more than one M+C plan at any given time. Comments on the M+C eligibility rules are discussed below.

Comment: Several commenters objected to the omission from the regulations of any provision permitting individuals to remain enrolled with an organization upon becoming Medicare eligible if they were enrolled with the organization as a commercial enrollee, but live outside the Medicare service area. In particular, commenters recommended that beneficiaries residing outside of an M+C plan's service area be allowed to remain enrolled with the M+C organization offering the M+C plan as an M+C plan enrollee upon becoming eligible for Medicare, even if they live outside the M+C service area. Commenters noted that the previous regulations in Part 417 that applied to section 1876 risk contracts allowed an individual enrolled with an organization as a commercial enrollee to remain enrolled with the organization as a Medicare enrollee upon becoming eligible for Medicare even if the individual did not live in the Medicare service area. Several commenters asserted that the continuation area option provided for in the BBA (discussed in further detail below) was not an adequate replacement for the previous option; they believe that prohibiting out-of-area members from voluntarily remaining enrolled in M+C plans unduly restricts the options available to beneficiaries and causes unnecessary disruptions in care. One commenter noted that section 1851(b)(1)(A) of the Act gives us the discretion to make an exception to the requirement that the individual reside in the M+C plan's geographic area.

Response: The last commenter is correct that section 1851(b)(1)(A) states that, "Except as the Secretary may otherwise provide (emphasis added), an individual is eligible to elect an M+C plan offered by the M+C organization only if the plan serves the geographic area in which the individual resides." In accordance with the statute, existing §422.250(a) generally limits eligibility to elect an M+C plan to individuals living in the plan's service area. The only discretion exercised by the Secretary in the M+C regulations was to permit individuals the option of continuing enrollment in the plan if they move out of the service area and into a plan's "continuation area" (which can be established pursuant to section 1851(b)(1)(B) of the statute and §422.254 of the M+C regulations, as discussed in detail below.)

Based on the comments we received on the interim final rule, however, as well as the reluctance of M+C organizations to establish formal continuation areas, we have become convinced that the regulations should be amended to provide for additional choices for beneficiaries. Thus, we are amending §422.50 (with conforming changes to §§422.66(d)(1) and 422.74(b)(2) and (b)(4)) to permit M+C organizations to offer a "seamless conversion" option to individuals who, upon becoming entitled to Medicare, live outside of an M+C plan's service area but are already enrolled in a commercial health plan offered by the same organization. If an M+C organization chooses to offer this option, it must offer the option to all individuals who were enrolled in a commercial health plan offered by the organization at the time they become Medicare-eligible. We do not believe it is appropriate to limit the availability of this option only to beneficiaries who had previously been enrolled in employer group health care plans, but instead are providing that both individual and employer group members of commercial health plans may elect to remain enrolled with their organization under an M+C plan under an expanded "seamless conversion" option. Similarly, we note that this expanded eligibility requirement is not limited to situations in which an enrollee becomes eligible for Medicare by virtue of age (referred to in the past as “age in” enrollees), but will apply to all newly eligible Medicare beneficiaries, including the ESRD and disabled population. (As noted above, we previously determined, in the interim final rule, that people with ESRD who are enrolled with an organization before becoming Medicare eligible may remain enrolled with the organization as an M+C plan enrollee.) We note that organizations that wish to offer this option must meet the M+C access standards under §422.112, and must furnish the same benefits to these enrollees as to enrollees who reside in the plan service area. Such enrollees should be made aware by the M+C organization of the extent to which they will need to travel into the plan service area to obtain service.

Comment: One commenter pointed out that State-authorized managed long term care plans may identify a chronically ill target population to be served, while the M+C regulations at §422.50 do not allow an M+C plan to discriminate within an approved service area among those who are eligible to enroll in M+C plans. The regulations also do not provide for plans to enroll special populations. The commenter asked whether these provisions are waivable to permit plans authorized as managed long-term care plans under State law to participate in the M+C program.

Response: There is no authority in the statute to "waive" the requirement that M+C organizations accept all M+C-eligible individuals in the service area who wish to enroll. However, we have approved demonstration projects under independent demonstration authority that involve managed care entities that restrict Medicare enrollment to long-term care populations. Long-term care plans may be able to participate in Medicare under such a demonstration.

Comment: One commenter asked for clarification regarding whether individuals who are enrolled only in Medicare Part B or who have ESRD, and were grandfathered into M+C plans as of January 1, 1999, can move from plan to plan in the same M+C organization or to another organization. The commenter supported allowing the individual to move between plans and organizations. Another commenter suggested that we allow an individual enrolled only in Medicare Part B who retained his or her enrollment in an M+C plan as of January 1, 1999, to enroll in another M+C organization for a period of time after disenrolling from an M+C plan. In addition, the commenter suggested that individuals enrolled only in Medicare Part B should be able to enroll in an M+C plan at any time until 2002.

Response: We agree that grandfathered Part B-only individuals and individuals with ESRD should be allowed to move between plans within an M+C organization, and have specified that this is permissible in OPL 99.084, issued on February 26, 1999. With respect to beneficiaries with ESRD, this policy is based on section 1851(a)(3)(B) of the Act, which we interpret as permitting an existing enrollee who develops ESRD while enrolled with an organization to remain enrolled with that organization. This is an exception to the general rule that an individual medically determined to have ESRD is not eligible to enroll in an M+C plan. However, we do not have statutory authority to permit a beneficiary with ESRD to enroll in a plan offered by a different M+C organization. Similarly, under section 1851(a)(3) of the Act, Part B-only enrollees generally are ineligible to enroll in an M+C plan. Section 1876(k)(2) of the Act, however, permitted a Part B-only beneficiary enrolled with an organization under a section 1876 risk contract on December 31, 1998, to continue enrollment in that organization if the organization has entered into an M+C contract effective January 1, 1999. Again, we have no statutory authority to expand upon this exception by permitting that individual to enroll with a different M+C organization from the one in which he or she was enrolled on December 31, 1998, under a section 1876 risk contract.

Comment: One commenter stated that individuals enrolled only in Medicare Part B who disenroll from M+C should be permitted to immediately enroll in Medicare Part A, and the surcharge for late enrollment should be eliminated.

Response: Provisions affording such beneficiaries these protections have been in place for some time. The Omnibus Reconciliation Act of 1990 established the Transfer Enrollment

Period (TEP) during which individuals who have Part B only and whose coverage in a Medicare managed care plan is terminated for any reason may immediately enroll in Premium Part A. This provision is found at section 1818(c)(7) of the Social Security Act, and §406.21(f) of our regulations, which also provide for relief from the premium surcharge for late enrollment. Under the TEP provisions, individuals may enroll in Premium Part A during any month in which they are still enrolled in the managed care plan or during the 8-month period following the last month of coverage under the plan. Under certain circumstances enrollment may occur up to 3 months in advance. If the individual enrolls in Premium Part A while still enrolled in the managed care plan or during the first full month when not so enrolled, Part A coverage is effective with the month of enrollment or, at the individual's option, the first day of any of the following 3 months. If enrollment occurs during the 7 remaining months of the TEP, Part A coverage is effective the month after the month of enrollment.

Comment: One commenter suggested that the regulation be revised to permit individuals with ESRD who have been enrolled in a commercial plan or a Medicare Cost HMO offered by the M+C organization to enroll in an M+C plan of that organization.

Response: Existing §422.50(a)(2) provides this protection, stating that an individual who develops ESRD while enrolled in an

M+C plan, or in a health plan offered by the M+C organization offering an M+C plan in the area in which the individual resides, may continue to be enrolled in an M+C organization as an M+C plan enrollee. Also, consistent with section 1851(a)(3)(B) of the Act, we have specified in OPL99.084 that individuals with ESRD may move among plans within an M+C organization. (We note that under this final rule, the individual may remain enrolled even if he or she does not live in the service area if new §422.50(a)(3)(ii) applies.) For purposes of §422.50(a)(2), "a health plan offered by the M+C organization" includes any commercial health plan and any cost contract held by that organization. In the case of an individual who develops ESRD while enrolled in a commercial plan offered by a cost contractor, the section 1876 rules similarly allow such an individual to remain enrolled with that organization under its cost contract after becoming eligible for Medicare.

Comment: One commenter believes that we are interpreting the phrase "entitled to benefits under Part A and enrolled in Part B" incorrectly.

Response: Our interpretation of this phrase is explained in detail in the interim final rule (63 FR 34979), and we would refer the commenter to that detailed explanation. To briefly reiterate our reasoning, we believe that the Congress intended that a newly eligible individual be given the opportunity to be enrolled in an M+C plan only after he or she is actually entitled to receive benefits under Part A and Part B. This view is supported by language in section 1851(e)(1) of the Act, which refers to "the time an individual first becomes entitled to benefits under Part A and enrolled under Part B," and provides for the Secretary to specify an initial coverage election period under which such an individual may elect coverage under an M+C plan "effective as of the first date on which the individual may <u>receive</u> such [Part A and Part B] coverage" (emphasis added). While an individual technically may have "enrolled" in Part B once an application has been completed, such an individual's right actually to "receive" coverage of services under Part B may not occur for a period of months. (See 63 FR 34979.) Since M+C organizations are paid in part from Part B trust funds, we do not believe it would be appropriate for an individual to be enrolled in an M+C plan before he or she is entitled to "receive" Part B trust fund payments. We therefore have interpreted "enrolled in Part B" to mean entitled to receive Part B coverage. Consistent with section 1856(b)(2) of the Act (which provides for use of section 1876 standards to carry out analogous M+C provisions), this interpretation follows our longstanding interpretation of identical language in section 1876(d) of the Act.

2. Continuation of Enrollment (§422.54)

Section 1851(b)(1)(B) of the Act permits M+C organizations to offer enrollees the option of continued enrollment in an M+C plan when enrollees leave the plan's service area to reside elsewhere (that is, in the "continuation" area) on a permanent basis. M+C organizations that choose to offer a continuation of enrollment option must explain the option in marketing materials, and make it available to all enrollees in the service area of the plan. Enrollees may choose to exercise the option of continued enrollment when they move out of the plan's service area, or they may choose to disenroll.

An M+C organization must obtain our approval of the continuation area and related marketing materials, and meet the access requirements under section 1851(b)(1)(B) of the Act, before it may offer a continuation of enrollment option to Medicare beneficiaries.

The payment rate for the M+C organization is based on the rate and adjustment factors that correspond to the beneficiary's permanent residence. Under section 1851(b)(1)(B) of the Act, the M+C organization must, at a minimum, provide or arrange for the provision of Medicare-covered benefits under section 1852(a)(1)(A) of the Act in the continuation area. This does not include any additional benefits the organization is required to provide to noncontinuation area members under section 1852(a)(1)(B) of the Act.

Section 1851(b)(1)(B) of the Act requires that "reasonable access" be provided in the continuation area, and that enrollees be subject to "reasonable cost sharing." In the interim final rule, we required that M+C organizations satisfy the access requirements in §422.112, and provide services either through written agreements with providers or by making payments that satisfy the requirements in §422.100(b)(2).

We are defining "reasonable cost sharing" in the continuation area as limited to the cost-sharing amounts required in the M+C plan's service area (in which the enrollee no longer resides).

The interim final rule also provides that appeals and grievances of enrollees in the continuation area must be handled in the same timely fashion as for other enrollees. The ultimate responsibility for the handling of appeals and grievances is with the organization that is receiving payment from us.

We received 11 comments requesting further guidance regarding the continuation of enrollment option. Generally, commenters endorsed the continuation of enrollment concept and urged us to define continuation areas broadly in order to enhance coverage options for enrollees.

Comment: One commenter asked whether the beneficiary may choose the continuation area option verbally or in writing.

<u>Response</u>: Our current policy, as outlined in OPL 99.100 (which was published August 9, 1999), requires that the beneficiary choose the continuation area in writing, so that there is documentation of this choice. We further believe that in the absence of an affirmative choice to remain enrolled in an M+C plan under the different terms that apply to continuation enrollees, a move out of an M+C service area should be treated as a decision to disenroll from the M+C plan. We accordingly have amended §422.54(c)(2) to provide that a beneficiary's choice to continue enrollment in a continuation area must be made in a manner specified by us, and that in the absence of such a choice, the beneficiary will be considered to have chosen to disenroll from the M+C plan if he or she moves out of its service area.

<u>Comment</u>: Commenters recommended that the benefits in the continuation area should reflect the level of reimbursement the M+C organization receives, and thus should include any additional benefits.

<u>Response</u>: As the commenters point out, the existing continuation of enrollment regulations at §422.54(d) require, at a minimum, that M+C plans provide Medicare-covered services in the continuation area. We recognize that this permits M+C plans to offer less generous benefits in the continuation area while still receiving the full Medicare payment. Section 1851(b)(1)(B) of the Act provides that individuals exercising the continuation

of enrollment option have access to the "full range of basic benefits" described in section 1852(a)(1)(A) of the Act. However, section 1852(a)(1)(A) of the Act refers only to those benefits available under Parts A and B, and not to additional benefits, which are described in section 1852(a)(1)(B) of the Act. Thus, although we agree that it would be preferable that M+C organizations be required to provide additional benefits to continuation area enrollees, the statute does not support this requirement. Therefore, we are considering a legislative proposal that would correct this inequity.

Comment: Several commenters inquired about the process for applying to us for a continuation area.

Response: We are adding a continuation area chapter to the M+C application for new M+C organization applicants. A separate application form will be available for current M+C contractors who wish to apply for a continuation area. Further guidance regarding the application process will be available in a forthcoming OPL.

Comment: One commenter asked whether a member must use only Medicare-certified facilities in the continuation area.

Response: The pertinent requirements in §422.204(a)(3) apply equally to services furnished in a continuation area. Under §422.204(a)(3), benefits must be provided through, or payments must be made to, providers that meet applicable title

XVIII requirements. Further, a hospital, nursing home, home health agency, or other "provider of services" as defined in section 1861(u) of the Act, must have a provider agreement with us in place. (See section II.E of this preamble for further details on this requirement.) We believe these requirements help to assure the quality of care that is provided to beneficiaries.

Comment: Another commenter suggested that we allow M+C organizations a 1-year transition period to establish continuation areas and implement any continuation area requirements.

Response: We believe the regulations provide organizations with sufficient opportunity to implement continuation area requirements. M+C organizations are not required to establish a continuation area for their enrollees. Thus, an M+C organization may choose not to offer a continuation area until it is ready to implement the requirements outlined in §422.54.

Comment: One commenter questioned whether State licensing regulations may supersede the potential advantages or enrollment flexibility of the continuation area.

Response: We believe the commenter is questioning how State licensing requirements will affect an M+C organization's ability to establish or offer the continuation of enrollment option. Section 422.400(a) states that an M+C organization must be licensed under State law, or otherwise authorized to operate under State law, as a risk-bearing entity eligible to offer health insurance or health benefits coverage. Therefore, an M+C organization may establish a continuation area only in a State in which it is licensed under State law or otherwise authorized to operate. The individual States have the authority to determine whether they are going to require licensure or, for example, permit the M+C organization to use the licensure of an affiliate if it wishes to establish an out-of-State continuation area. Although we are not aware of State laws that unduly restrict the establishment of continuation areas, we would refer the reader to section II.I of this preamble for a detailed discussion of situations in which State laws are preempted by M+C laws and regulations.

Comment: Some commenters contended that we interpreted section 1851(b)(1)(B) of the Act too restrictively. For example, commenters objected to the requirement in §422.54 that an M+C plan's service area must be geographically distinct from its continuation area. Commenters also questioned whether enrollees who move to continuation areas in counties adjacent to the M+C plan's service area may continue to receive services in the M+C plan's service area.

Response: A continuation area, as defined at §422.54(a), is an additional area outside the service area in which the M+C organization furnishes or arranges for furnishing services to its enrollees. The regulation does not prohibit continuation areas adjacent to the M+C plan's service area, as the commenter appears to believe. Further, we agree that enrollees residing in a continuation area adjacent to the M+C plan's service area may receive services in the M+C plan's service area, as long as the access and service requirements of §422.112 are met.

Comment: One commenter suggested that we allow enrollees to obtain services in the continuation area, even if they are not living in the continuation area permanently.

Response: The continuation area is intended for those enrollees who reside permanently outside of the service area (and permanently inside the continuation area) and want to remain enrolled in the plan. We do not have the authority to direct M+C plans to offer enrollees, temporarily residing in the continuation area, benefits in excess of the urgent/emergent care required by the statute and those benefits voluntarily offered by an M+C plan in its traveler/visitor policy.

Comment: One commenter requested clarification regarding whether the continuation of enrollment option is intended to replace current travel programs. The commenter also inquired whether an enrollee would remain enrolled for the first 12 months with coverage only for emergency and urgently needed care, and then convert to a continuation of enrollment option.

<u>Response</u>: The continuation of enrollment option is not designed to replace current travel programs. In general, the purpose of traveler/visitor programs is to allow enrollees the opportunity to continue obtaining health care services while traveling outside the service area of the M+C plan in which they are enrolled. In contrast, the continuation of enrollment option is intended to permit enrollees to remain enrolled with an M+C plan if they move permanently outside of the plan's service area. If the enrollee moves permanently into an area other than a continuation area, the member must be disenrolled as soon as the M+C organization is aware of the move and the enrollee has been notified. If an enrollee moves permanently into a geographic area designated as a continuation area, and chooses to remain a member of the M+C plan as a continuation of enrollment member, the enrollee must receive, at a minimum, Medicare-covered services. If an enrollee moves temporarily into the continuation area, or any area outside the service area, the M+C plan must provide coverage for emergency and urgently needed care. With respect to the question of whether an enrollee would remain enrolled for the "first 12 months" after a move, before converting to a continuation enrollment option, an individual can be a continuation enrollee as soon as he or she moves permanently to the continuation area. There is no waiting period.

3. Election Process (§422.60)

The general rule for acceptance of enrollees is that, except for the limitations on enrollment in an M+C MSA plan (§422.62(d)(1)), and for cases in which a plan has reached its enrollment capacity, each M+C organization must accept without restriction eligible individuals who elect an M+C plan during initial coverage election periods, annual election periods, and special election periods specified in §§422.62(a)(1), (a)(2), and (b).

Additionally, M+C organizations must accept elections during the open enrollment periods specified in §§422.62(a)(3), (a)(4), (a)(5), and new (a)(6) if their M+C plans are open to new enrollees.

We stated in the interim final rule that the election form must comply with our instructions regarding content and format and have been approved by us as described in §422.80. The form must be completed and signed by the M+C eligible individual (or the individual who will soon become entitled to Medicare benefits) and include authorization for disclosure and exchange of necessary information between the DHHS and its designees and the M+C organization. Persons who assist beneficiaries in completing forms must sign the form and indicate their relationship to the beneficiary.

We further stated that the M+C organization must file and retain election forms for the period specified in our instructions. An election in an M+C plan is considered to have been made on the date the election form is received by the M+C organization. Also, the M+C organization must have an effective system for receiving, controlling, and processing election forms that requires that each election form is dated as of the day it is received and election forms are processed in chronological order, by date of receipt. Additionally, the M+C organization must give the beneficiary prompt written notice of acceptance or denial in a format specified by us. We also provided that a notice of acceptance, in a format specified by us, informs the beneficiary of the date on which enrollment will be effective under §422.68; and if the M+C plan is enrolled to capacity, explains the procedures that will be followed when vacancies occur. Also, a notice of denial explains the reasons for denial in a format specified by us. Within 30 days from receipt of the election form (or from the date a vacancy occurs for an individual who was accepted for future enrollment), the M+C organization transmits the information necessary for us to add the beneficiary to our records as an enrollee of the M+C organization.

Comment: Several commenters had concerns with allowing M+C organization representatives to assist individuals in completing any part of the election forms. One commenter believes that the common practice should be the beneficiary completing and signing his or her own form. Another commenter believes M+C organizations should be allowed to assist beneficiaries in completing the election forms only in limited circumstances, such as if the enrollee is disabled and needs assistance, and that organizations abusing this process should be subjected to meaningful penalties. One commenter suggested that when assistance is provided to a beneficiary in completing the election form, a reason for the assistance also be documented on the form, especially if an M+C organization agent completes the form. In contrast, two commenters supported a provision that permits individuals to assist a Medicare beneficiary in completing an election form.

Response: As discussed in the preamble of the interim final rule (63 FR 34984), section 1851(h)(4)(B) of the Act indicates that the "fair marketing standards" may include a prohibition against an M+C organization (or agent of such an organization) completing any portion of any election form used to carry out elections on behalf of any individual. However, we have decided at this time not to prohibit an M+C organization (or agent of such an organization) from assisting beneficiaries in completing the election form. We recognize that we must provide accommodations for persons with disabilities and for situations in which such a prohibition could represent a potential physical burden to beneficiaries. We believe requiring the signature of the individual who assisted the beneficiary in completing the form and an indication of his or her relationship to the beneficiary is a fair compromise.

We agree that the M+C organization should be allowed to assist beneficiaries in completing the election form only under limited circumstances. For this reason, representatives should be assisting the beneficiary in completing the election forms only when assistance is needed, such as for a person who is disabled, illiterate, or otherwise impaired by age or health. In fact, in some circumstances assistance may be required to comply with civil rights requirements, for example, to ensure that individuals with disabilities or limited English proficiency have an equal opportunity to participate. Any M+C organization that unduly influences beneficiaries through this assistance should be identified by our monitoring procedures and subject to sanctions as specified in §422.750.

We believe requiring the signature and identifying their relationship to the individual who is enrolling in the M+C plan is a sufficient beneficiary protection. It provides adequate information to monitor a beneficiary's understanding that the form is for enrollment. The reason why an individual needs assistance should not be included on the enrollment form because it could undermine a Medicare beneficiary's right to privacy by disclosing health related information without his or her consent.

Comment: One commenter asked how enrollment and disenrollment requirements under Medicare compare to Medicaid rules, which the commenter erroneously believes allow the enrollee to enroll and disenroll at any time.

Response: Dually eligible individuals, that is, those individuals who are entitled to Medicare as well as Medicaid, have the same freedom of choice under Medicare as those who are entitled to Medicare only. M+C election provisions under section 1851(e) of the Act and §422.62 of our regulations apply to all M+C-eligible individuals, and prior to 2002, permit Medicare enrollees to disenroll at any time. Under Medicaid rules, in contrast, managed care organizations (MCOs) are permitted to preclude Medicaid enrollees from disenrolling without cause for up to a year. MCOs are required only to permit disenrollment without cause in the first 90 days of enrollment, and annually thereafter. See section 1932(a)(4) of the Act.

Comment: One commenter requested clarification on when M+C organizations are required to be open for enrollment. In particular, the commenter expressed confusion over the meaning of the term "open enrollment period."

Response: We recognize the potential for confusion associated with the use of the term "open enrollment period." In accordance with section 1851(e)(6)(A) of the statute, §422.60(a)(1) specifies that M+C organizations must be "open for enrollment" (that is, must accept enrollments) during annual, initial coverage, or special election periods unless they have reached enrollment capacity. However, under section 1851(e)(6)(B) of the Act, an M+C organization may accept elections at <u>such other</u> times as the organization provides. These latter time periods, during which an M+C organization has the discretion to decide whether to be "open" for enrollment are frequently referred to as "open enrollment" periods. We note that, if an M+C organization chooses to be open to new enrollees during all or a portion of these discretionary "open enrollment" periods, it must be open for all M+C-eligible individuals.

<u>Comment</u>: One commenter found §422.60(a)(2), which states that M+C organizations must accept elections during open enrollment periods if their plans are open to new enrollees, to be confusing and detrimental to newly eligible individuals. The commenter believes that new Medicare eligibles should not be limited to these time frames.

<u>Response</u>: The new enrollees being referred to in §422.60(a)(2) are individuals newly electing the M+C plan and not individuals newly eligible for Medicare. Individuals newly eligible to Medicare are given a different "open enrollment" period under which they may elect or change M+C plans. In particular, §§422.62(a)(4)(ii) and 422.62(a)(5)(ii) allow newly eligible individuals to make an election beginning the month the

individual is entitled to Medicare Parts A and B and ending on the last day of the sixth month of entitlement (in 2002) or the third month of entitlement (in 2003 and thereafter) or on December 31, whichever is earlier. Therefore, we do not believe a regulatory change is necessary.

Comment: One commenter asked if we would be modifying our enrollment transmission schedule to account for the 30-day period in which the M+C organization must transmit the enrollment information as stated in §422.60(e)(6).

Response: Based on this comment, we are amending §422.60(e)(6) to state that "upon receipt of the election form (or from the date a vacancy occurs for an individual who has been accepted for enrollment), the M+C organization transmits the information, within time frames specified by us, necessary for us to add the beneficiary to our records as an enrollee of the M+C organization." We are also revising §422.60(f)(3) to state that "upon receipt of the election form from the employer, the M+C organization must submit the enrollment within time frames specified by HCFA." These changes will allow us the flexibility to vary the time frames in the future, should technological or policy changes warrant it.

Comment: One commenter asked that we clarify and provide guidance as to when an election is considered to have been made.

<u>Response</u>: Section 1851(f)(2) of the Act, as revised by section 502 of the BBRA, states that the effective date of coverage during continuous open enrollment periods is the first day of the first calendar month following the date on which the "election is made," except that if the election or change of election is made after the 10th day of a calendar month, the election or change of election takes effect on the first day of the second calendar month following the date on which the election or change is made. As noted in the preamble of the interim rule, it was necessary to define when an election is made in order to establish the effective date of coverage and to establish the date of our liability for payment. Therefore, the regulations at §422.60(d) state that an election is considered to have been made on the date it is received by the M+C organization.

4. Enrollment Capacity (§422.60(b))

Sections 422.60(b) and 422.306(a) of the original M+C regulations required M+C organizations to submit information on the enrollment capacity of plans they offer by May 1 of each year. As noted in section I.C.8 of this preamble, section 516 of the BBRA amended section 1854(a)(1) of the Act to move the annual deadline for submission of ACR proposals and enrollment capacity data (if any) from May 1 to July 1, effective in 1999. If a plan reaches its HCFA-approved capacity limit, the M+C organization offering the plan generally is not obligated to accept new enrollees.

Comment: One commenter requested that we change the date that M+C organizations must notify us of the need for a capacity limit from May 1 to a date later in the year in order to allow the M+C organizations more time to analyze the previous year's capacity and better determine the need for a capacity waiver.

Response: While we had no discretion under the BBA to make the change in question, as just noted, Congress has done so. We have revised §§422.60(b)(1) and 422.306(a)(1) to reflect this BBRA change.

Comment: A commenter asked that we clarify our language on capacity limits within a service area. The commenter also asked what would happen if there are too many patients and too few providers.

Response: Section 422.60(b) allows an M+C organization to limit enrollment in the M+C plans it offers during any enrollment period, subject to our approval. If an M+C organization elects to establish a capacity limit for an M+C plan, the request normally must be submitted to us at the time the Adjusted Community Rate Proposal (ACRP) is submitted (except as provided in new §422.60(b)(3)), as discussed below. This submission should take into account the number of providers, and how many patients they can serve. The situation described by the commenter, in which “there are too many patients and too few providers” generally should not occur if capacity is limited to the number submitted by the M+C organization on July 1.

As the commenter suggested, however, we recognize that under certain circumstances, there may be a legitimate need for an M+C organization to request a capacity limit or a revision of a capacity limit for an M+C plan during the contract year. The circumstances under which a capacity limit will be approved after the ACRP date would likely occur when a portion of a provider network that furnishes services under an M+C plan becomes unavailable during the course of a contract year. We have provided for HCFA to consider enrollment capacity requests outside of the ACR process under new §422.60(b)(3), which permits consideration of such requests only if the health and safety of beneficiaries is at risk, such as if the provider network is no longer available to serve enrollees in all or a portion of the service area. The requirements for a midyear capacity limit request are also described in OPL99.095.

5. Election of Coverage Under an M+C Plan (§422.62)

All M+C plans must be open to M+C-eligible enrollees residing in the service area served by the plan during initial coverage election periods, annual election periods, and special election periods, unless such enrollment in the plan is limited based upon a limit on enrollment capacity.

The initial coverage election period is the period during which a newly M+C-eligible individual may make an initial election. This period begins 3 months prior to the month the individual is first entitled to both Part A and Part B and ends the last day of the month preceding the month of entitlement. An election made during this period is effective when entitlement to Part A and Part B coverage begins.

The month of November is the annual election period for the following calendar year. During the annual election period, an individual eligible to enroll in an M+C plan may change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan. This election is effective on January 1.

Special election periods are periods during which enrollment must be made open to certain beneficiaries, for various reasons specified in the statute, or by us. We specify the effective date of elections made during special election periods.

M+C plans may be open to new enrollees at other times of the year (that is, during open enrollment periods) at the discretion of the M+C organization offering the plan.

From 1998 through 2001, the number of elections or changes that an M+C-eligible individual may make is not limited (except for M+C MSA plans). Subject to the M+C plan being open to enrollees as provided under §422.60(a)(2), an individual eligible to elect an M+C plan may change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan any number of times. In 2002, an individual who is eligible to elect an M+C plan in 2002 generally may elect an M+C plan or change his or her election from an M+C plan to original Medicare or to a different M+C plan only once during the first 6 months of that year. For 2003 and subsequent years, an individual who is eligible to elect an M+C plan generally may elect or change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan only once during the first 3 months of the year. (Note that consistent with section 501(b) of the BBRA, the restrictions that begin in 2002 do not apply to institutionalized individuals.)

Even after the above limitations on changes in elections are in place, if certain circumstances exist, an individual may discontinue the election of an M+C plan offered by an M+C organization and change his or her election to original Medicare or to a different M+C plan. These circumstances include:

- when the individual is no longer eligible to be enrolled in a certain plan due to a change of residence,
- when HCFA terminates the organization's contract for the plan, or the organization terminates the plan or

discontinues offering the plan in the service or continuation area in which the individual resides,

! when the M+C organization has violated a material provision of its contract or materially misrepresented the plan's provisions in marketing the plan to the individual, or

! when the individual meets such other exceptional conditions as we may provide.

Comment: Several commenters expressed concern because the new M+C election periods do not coincide with the time frames under which M+C eligible individuals elect health benefit options through their employer group health plans. The commenters believe these individuals should not be subject to the M+C election periods. One commenter pointed out that employer groups will experience considerable disruption in their yearly enrollment process, and, as a result, may have to stop offering their retirees wrap-around coverage to M+C plans, or they will have to modify their entire enrollment process.

Response: Section 422.62(b) states that we may grant special election periods for individuals who meet exceptional conditions. We have determined that the dilemma addressed by the commenters presents an "exceptional condition" that justifies the establishment of a special election period for M+C-eligible individuals who are members of an employer group plan that has open enrollment at a time other than the month of November. This is because such an individual could only change one part of his or her coverage at a time, which effectively would lock the beneficiary into his or her existing plan. As set forth in OPL 99.100, such M+C-eligible individuals may choose to elect an M+C plan offered by their employer during their employer group’s open season, which constitutes a special election period for these individuals, as well as during the other election periods established under section 1851(e) of the Act.

Comment: Several commenters were opposed to the establishment of "lock-in" requirements beginning in 2002. They believe it will eliminate competition created in an environment where managed care plans compete continuously for enrollments. Several commenters also wanted to know who will be responsible for keeping track of the number of elections made by an individual once lock-in takes effect in 2002. They noted that beneficiaries and M+C organizations may not be aware of the number of elections an individual has made during a particular election period. One commenter recommended that we develop a mechanism that will allow exceptions to the limit of one change under §§422.62(a)(4) and (5).

Response: Sections 1851(e)(2)(B) and (C) of the Act limit an individual's election to one change during the open enrollment periods in the first 6 months of 2002 and the first 3 months of subsequent years. This "lock-in" requirement represents a gradual transition from the current system, under which a beneficiary may make any number of elections during the continuous open enrollment periods outlined in section 1851(e)(2)(A) of the Act to a restrictive system of annual "lock-in." We do not have the authority to modify this requirement, or to provide for any exceptions to this limit. We are aware of the need for us to maintain a history of the number of times an individual has made an election during a specific election period. Such information will be necessary in order to determine whether an individual is eligible to elect an M+C plan at a given time.

Comment: One commenter believes that limiting the open enrollment and disenrollment opportunities defined in §§422.62(a)(4) and (5) to one election per period should not apply to plan changes within the same M+C organization.

Response: Section 1851(a)(1) of the Act requires that an M+C-eligible individual "elect" to receive benefits through the original Medicare fee-for-service program or through enrollment in an M+C "plan." That is, enrollment in an M+C "plan" constitutes an election under Part C. Section 1851(e) of the Act further limits the "election" of an M+C "plan" or of original Medicare to one change during open enrollment periods in the first 6 months of 2002 and the first 3 months of subsequent years. Therefore the law does not permit us to allow M+C-eligible individuals to move from plan to plan without considering it an election, even if the change in plans occurs among plans offered by the same M+C organization.

Comment: One commenter requested further clarification of enrollment and disenrollment periods, while another asked whether a beneficiary who defaults to original Medicare has the option to elect an M+C plan.

Response: An individual who defaults to original Medicare may elect another M+C plan during any election period during which the plan is accepting new enrollments. As discussed in detail above, section 1851(e) of the Act and §422.62 of the M+C regulations describe the election periods in which individuals can enroll in and disenroll from an M+C plan. M+C-eligible individuals may make or change an election during an initial coverage election period, an annual election period, a special election period, or an "open enrollment" period. The initial coverage election period is the 3-month period prior to the month an individual becomes entitled to Medicare Part A and Part B. The annual election period is November of every year. Special election periods are also allowed when M+C-eligible individuals experience certain circumstances that warrant the need to make a change in election. These include our termination of the M+C plan contract or M+C organization termination or discontinuance of the M+C plan in the service or continuation area in which the individual resides, a change in place of residence to a place outside of the M+C plan's service or continuation area, demonstration by the individual that the M+C organization substantially violated a material provision of its contract or materially misrepresented the M+C plan's provisions in marketing materials, or other exceptional conditions as provided by us. In addition, §422.62(c) also provides for a special election period for individuals age 65. Beginning in 2002 individuals age 65 who elect an M+C plan during the initial enrollment period may disenroll from the M+C plan and elect coverage under original Medicare within 12 months of their enrollment in an M+C plan.

Through 2001, open enrollment periods are continuous, that is, every month through 2001. Beginning in 2002, the open enrollment periods are the first 6 months of the year, or the first 6 months of Medicare Part A and Part B entitlement (or December 31, 2002, whichever is earlier). In 2003 and in subsequent years, the open enrollment periods are the first 3 months of the year, or the first 3 months of Medicare Part A and Part B entitlement (or December 31, 2003, whichever is earlier). Again, open enrollment periods remain continuous for institutionalized individuals during and after 2002.

The election rules for M+C MSA plans (see §422.62(d)) include some exceptions to the election periods described above.

M+C-eligible individuals may only enroll in an MSA plan during an initial coverage election period or an annual election period. They may not make an election of an MSA plan during open enrollment periods or special election periods. M+C-eligible individuals may only disenroll from an MSA plan during annual election periods and special election periods, excluding special election periods for individuals age 65. In addition, if an individual elects an M+C MSA plan for the first time during the annual November election period, he/she may revoke that election by December 15 of that same year.

Comment: One commenter supported the special election period for individuals age 65 as outlined at §422.62(c), and requested that the provision also apply to newly eligible individuals with disabilities.

Response: Section 422.62(c) implements the last sentence in section 1851(e)(4) of the Act, which applies only to individuals who enroll in an M+C plan upon turning 65. Congress chose to provide this opportunity to individuals who become eligible based on age, but did not provide for such a benefit in the case of individuals who become eligible based on disability or ESRD status. We thus cannot apply section 1851(e)(4) of the Act to individuals who are not 65, since they do not meet an explicit condition set forth in the statute.

Comment: One commenter noted that §422.62(b)(3) allows an individual a special election period if the M+C organization violates a material provision of its contract with the individual. However, it does not allow the M+C organization an opportunity to comment on the enrollee's assertion that the contract was violated. The commenter stated that we should be sensitive to the severity of this issue and should establish a timely and fair review process. Two other commenters stated that we should develop reasonable, consistent guidelines for establishing special election periods for exceptional conditions, as provided at §422.62(b)(4).

Response: Section 1851(e)(4) of the Act gives us the authority to develop guidelines to establish special election periods for exceptional conditions and to establish the procedures for granting a special election period for contract violations that specify when individuals are entitled to disenroll from an M+C plan after disenrollment rights become limited in 2002. This authority provides us with the discretion and the time to develop beneficiary protection requirements that will be sensitive to the issues identified by the commenters. As we gradually transition from the current system of totally free movement to a restrictive system of annual "lock-in," we have every intention of developing reasonable and consistent guidelines as the need for these guidelines in the year 2002 approaches.

Comment: One commenter requested that we clarify at §422.62(a)(2)(ii) that eligible beneficiaries may elect to enroll in managed care demonstrations, section 1876 cost plans, and health care prepayment plans during the annual election period.

Response: The annual election period is an election period for M+C organizations operating under section 1851 of the Act. Health care prepayment plans, section 1876 cost plans, and some managed care demonstrations do not fall under section 1851 of the Act. Therefore, we do not have the authority to require these plans and demonstrations to be open for enrollment during an annual election period. Although such plans and demonstrations have the option of being open for enrollment to eligible individuals during that same time frame, this regulation only addresses requirements under section 1851 of the Act.

6. Information about the M+C Program (§422.64)

a. Overview

Section 422.64 contains requirements related to information about M+C plans. Paragraph (a) applies to M+C organizations, and requires that organizations annually provide to us, using a prescribed format and terminology, the information we need to carry out our annual information campaign for all Medicare beneficiaries. However, the remaining paragraphs of existing

§422.64 essentially reflect statutory provisions governing our information distribution activities.

Comment: Several commenters expressed confusion about whether we or M+C organizations were responsible for various information distribution requirements specified under §422.64.

Response: We recognize the commenter's concerns and believe that the best means to avoid introducing confusion in this regard is to eliminate from the regulations the portions of §422.64 that serve solely to delineate our responsibilities. Deleting these provisions from the Code of Federal Regulations in no way affects our information distribution responsibilities that had been reflected in these provisions, since these are set forth in the statute in sections 1851(d)(1) through (d)(4) of the Act. Also, we note that §422.111 continues to list the information that M+C organizations are responsible for disseminating to their plan enrollees.

Comment: Two commenters were concerned that the many changes introduced by the M+C program to the plan enrollment and disenrollment process (for example, changes to the effective date, annual open enrollment, lock-in requirements) would lead to beneficiary confusion and disruption of the program, and stressed the need for improved communication with beneficiaries.

Response: We agree that the many changes necessary for the implementation of the M+C program will require that we carry out substantial educational efforts for beneficiaries and the health industry. We are strongly committed to keeping beneficiaries informed and educated about their choices, and have undertaken many efforts to accomplish this task. For example, we have created a toll-free line for M+C information (1-800-MEDICARE), developed the Medicare & You handbook, and have carried out special educational and publicity campaigns to inform M+C-eligible individuals about the availability of plans offered in different areas and about the election process. In 1999, we began conducting a nationally coordinated educational and publicity campaign about M+C plans and the election process that occurs every November. We also provide information via our Internet website (www.Medicare.gov), which is a Medicare beneficiary-centered consumer website designed to provide a broad array of information on program benefits and health promotion. These are just a few of the many efforts we have begun to disseminate information to beneficiaries and prospective beneficiaries on their coverage options under the M+C program, and we believe that they should alleviate the potential confusion associated with the M+C program.

b. Access

Comment: A commenter recommended that §422.64 specifically require notification and disclosure of Medicare's screening Pap smear benefit and of the ability of beneficiaries to directly access specialists to obtain this preventive service.

Response: The 2000 Medicare & You handbook includes a description of the new preventive benefits. With respect to direct access to a specialist who would perform a pap smear, §422.112(a)(3) guarantees female M+C enrollees "direct access to a women's health specialist within the network for women's routine and preventive health care services," which would include Pap smears (see section II.C of this preamble for further details on this issue.)

c. Performance Measures

Comment: Several commenters expressed concerns about the validity, reliability, and comparability of information to be provided by us to Medicare beneficiaries, particularly through Medicare Compare, our Internet-based database of comparative information on M+C plans. The commenters want us to ensure that the information presented to beneficiaries is objective, accurate, and complete. They also emphasize the importance of recognizing the audience for particular types of information.

Response: Medicare Compare is our electronic database of health plan comparison information. The database is designed to educate beneficiaries and others about their health care options so they can make informed health care choices. The information for this database is compiled by us with cooperation from M+C organizations. The Medicare Compare database is also updated regularly to reflect changes in cost and benefits. We are continuing to implement enhancements to ensure that the data submitted by M+C organizations are valid and reliable. Medicare also collects quality-of-care information known as Health Plan Employer Data and Information Set (HEDIS) from M+C organizations and we carefully check it for accuracy. This information should help beneficiaries compare the quality of health care that an M+C organization delivers by explaining how well the organization keeps enrollees healthy or treats them when they are sick. Medicare's Consumer Assessment of Health Plans Study (CAHPS), developed in collaboration with the Agency for Healthcare Research and Quality, is an initiative to collect and report information on beneficiaries' experience in receiving care through M+C organizations. We have also worked closely with the industry and researchers in order to provide the most accurate information for the Medicare & You 2000 handbook.

d. Continuation and Improvements

Comment: Commenters were concerned about the amount of information provided to Medicare beneficiaries by us. They recommend that the information specified in §422.64 be included in the general information brochures and contain the customer service telephone numbers for each M+C organization. They also suggested that we need to differentiate between information provided to beneficiaries in written form, and that available to interested persons via the Internet. Written comparative information, which is to be available to all beneficiaries at specified intervals, should be easy to understand and focused in content.

Response: We provide access to information from a variety of sources. Beneficiaries, M+C organizations, providers, family members, and others can receive up-to-date information about the Medicare health plans available in their area, Medicare health benefits, fraud and abuse, nursing homes, appeals and grievances, patient rights, etc., at the following locations:

- Internet at www.Medicare.gov. Local libraries or senior centers may be able to help the person find the information on their computers.
- Medicare Choices Help line at 1-800-MEDICAR(E) and TTY for the speech and hearing impaired at 1-877-486-2048.
- State Health Insurance Assistance Program (SHIP) in the beneficiary's area.
- Local outreach events.

Comment: Several commenters encouraged us to evaluate all aspects of the information campaign in order to determine the most effective approach for reaching beneficiaries.

Response: We aim for timely distribution of all of our materials. We are legislatively mandated to mail specified information on the M+C program and individual M+C plans to beneficiaries at least 15 days prior to the annual election period. We are evaluating the impact of this timing on beneficiary decision making. Our ongoing evaluation of National Medicare Education Program (NMEP) includes assessment of telephone referrals, including toll-free line and State Health Insurance Assistance Programs (SHIPs), which are entities jointly funded by us and by the States to provide information and counseling to Medicare beneficiaries. The toll-free line has been operational nationally since March 15, 1999.

e. Beneficiary Input

Comment: Several commenters noted that in developing any educational materials or activities, it is important to ensure that the information is meaningful to beneficiaries. These commenters believe that we need to convey information to beneficiaries in an organized, straightforward manner to assure as complete an understanding as possible. For example, the commenters suggest that materials should be reviewed to determine whether they will provide needed information or simply raise more questions among beneficiaries, or whether beneficiaries will understand that they do not need to make any changes. The commenters specifically recommended that we conduct focus groups to gauge beneficiary responses to the Medicare & You handbook, and would like us to revisit our future plans and communications.

<u>Response</u>: We have performed extensive evaluation of the Medicare & You handbook, including focus-testing the Medicare & You 1999, and customer-testing of the Medicare & You 2000. We also used the results of the NMEP evaluation, survey of beneficiaries, expert review, plain language review, and comments submitted to us by mail and the Internet. The results received from all of these sources were used in the development of the Medicare & You 2000 handbook. We will continue evaluating our efforts to improve beneficiary communication.

<u>Comment</u>: Two commenters offered suggestions on the public input approach outlined in the preamble of our June 26, 1998 interim final rule. (In that preamble, we discussed in detail the process of obtaining public input about data collection and dissemination of selected data. We addressed only those data elements that would be disseminated as part of Medicare Compare or as part of any beneficiary information campaign efforts.) One commenter suggested ensuring that physicians are involved in determining data specifications for M+C organizations, and the other looked forward to seeing our strategy for public input.

<u>Response</u>: As discussed in the interim final rule, we recognize the importance of obtaining public input on data needed by beneficiaries to make health plan choices. We also agree that we need to ensure physician input, particularly in areas such as quality of care. Our strategy for obtaining public input into the

process, which is well under way and wide ranging, includes the following:

- Obtaining public input through currently established communication activities (for example, committees, consultation avenues, public meetings, training seminars). Limited resources and time demands do not permit the establishment of separate or overlapping processes with those already established and working (such as industry council meetings). It may not always be possible to hold public meetings to invite interested individuals to comment and provide input on the process of determining data specifications.

- Obtaining public input through normal data collection clearance channels when we are the lead for the data collection activity. The OMB clearance process is a very effective and efficient way to obtain broad public comment on the content and format specifications for data collection (for example, the Plan Benefit Package). However, it may not always be possible to publish a notice or a summary of public processes regarding data elements to be collected.

- Obtaining public input through collaborative efforts with private industry, health care providers, researchers, and other interested parties. This approach allows the Federal government to be a partner with other experts (private and public) in the field of managed care and thereby not duplicate already successful and useful collaborative efforts (such as HEDIS).

Thus, our strategy strongly supports the use of efficient and effective methods of public input into the determination of information and specifications for beneficiary information campaign material. We also recognize the need to collaborate with organizations and individuals involved in the development of quality and performance measurements that support beneficiaries' increased understanding of managed care.

7. Coordination of Enrollment and Disenrollment Through M+C Organizations (§422.66)

An individual who wishes to elect an M+C plan offered by an M+C organization may make or change his or her election during the election periods specified in §422.62 by filing the appropriate election form with the organization or through other mechanisms as determined by us.

Additionally, an individual who wishes to disenroll from an M+C plan may change his or her election during the election periods specified in §422.62 by either electing a different M+C plan by filing the appropriate election form with the M+C organization or through other mechanisms as determined by us. Individuals may also disenroll by submitting a signed and dated request for disenrollment to the M+C organization in the form and manner prescribed by us or by filing the appropriate disenrollment form through other mechanisms as determined by us.

Under existing §422.66(d)(1), an M+C plan offered by an M+C organization must accept any individual (residing in the service area or continuation area of the M+C plan) who is enrolled in a health plan offered by the M+C organization (regardless of whether the individual has end-stage renal disease--see §§422.50(a)(2) and (a)(3)) during the month immediately preceding the month in which he or she is entitled to both Part A and Part B. This is generally known as a "conversion" of enrollment for the enrollee (from commercial status to M+C enrollee status).

Subject to our approval, under §422.66(d)(2), an M+C organization may set aside a reasonable number of vacancies in order to accommodate conversions. Any set aside vacancies that are not filled within a reasonable time must be made available to other M+C-eligible individuals.

If the individual enrolled in a health plan offered by an M+C organization chooses to remain enrolled with the organization as an M+C enrollee, the individual must complete and sign an election form as described in §422.60(c)(1). In that case, the individual's conversion to an M+C enrollee is effective the month in which he or she is entitled to both Part A and Part B. The M+C organization may disenroll an individual who is converting from its commercial plan to M+C status only under the conditions specified in §422.74. The M+C organization must transmit the information necessary for us to add the individual to our records as specified in §422.60(e)(6).

An individual who has made an election under this section is considered to have continued to have made that election until the individual changes the election under this section or the elected M+C plan is discontinued or no longer serves the service area in which the individual resides, and the organization does not offer, or the individual does not elect, the option of continuing enrollment, as provided in §422.54, whichever occurs first.

Comment: Several commenters stated that they support procedures that would permit seamless continuation of coverage, under which an individual would be deemed to have elected an M+C plan at the time of the individual's initial coverage election period if they are enrolled in a commercial health plan that is offered by the same M+C organization. Several specific recommendations were made. One commenter recommended that we require M+C organizations to prospectively provide the necessary information that would allow us to default individuals into the M+C plan. One commenter recommended that M+C organizations notify individuals in their commercial plans who are about to become Medicare eligible that they are being enrolled in the M+C plan, and to transmit the necessary information to us. Another commenter suggested that we alert individuals through the mailing of the initial enrollment package. Two commenters were concerned about deeming an individual to have elected an M+C plan if the M+C organization offers more than one M+C plan from which he/she could receive benefits. One commenter suggested that if we decide to deem an individual to have elected an M+C plan, the organization should be required to provide the individual with a description of Medigap guaranteed issues and age rating policies. One commenter supported procedures that would permit seamless continuation of coverage, but expressed concerns about deeming an individual enrolled in an M+C plan if Medicare is a secondary payer.

Response: Although we have addressed an individual’s right to choose to remain enrolled with an organization as an M+C enrollee upon becoming Medicare eligible (as discussed above), a default process through which an individual would be deemed by us to have elected a specific M+C plan would require that we identify M+C-eligible individuals, as well as their relevant health plan information before the individual's initial coverage election period. At present we do not have access to information on the health plans in which specific individuals are enrolled, because such plans are private health plans, and do not have established linkages with our systems, nor is there a mechanism in our Medicare managed care data system to capture such information. While some M+C organizations may want to share this information with us, others may not. It should also be noted that enrollment in an M+C plan is contingent upon the individual's entitlement to Medicare Part A and Part B. Individuals that have not previously filed for Social Security and/or Medicare benefits will not have an entitlement record, nor will they receive an initial enrollment package from Medicare. Frequently, individuals in commercial plans who are about to "age in" to Medicare are still employed, and have not yet filed for Social Security or Medicare benefits. Individuals who have filed for benefits will receive general information on Medicare and comparative information on M+C plans available in their service area. They will have the opportunity to enroll in the M+C plan 3 months prior to their entitlement to Medicare Part A and Part B.

The expansion of the managed care provisions under the BBA has presented an extraordinary challenge to us and to the Medicare managed care data system that supports our information system business requirements. We anticipate that in the future, we will develop strategies to incorporate information collection activities in our managed care systems that will allow this kind of mechanism to be put in place. As we develop strategies that will incorporate additional information collection activities under our authority under section 1851(c)(2) of the Act, we will consider procedures necessary to identify in which plan a beneficiary wants to enroll if the M+C organization offers more than one M+C plan and also whether Medicare Secondary Payer rules apply. Until that time, and in accordance with §422.66(d), an M+C plan offered by an M+C organization must accept enrollments from any eligible individual residing in the service area or continuation area of the M+C plan, who is enrolled in a commercial health plan offered by that same M+C organization during the month immediately preceding the month in which he/she is entitled to Medicare Part A and Part B.

Comment: Two commenters were opposed to the requirement in §422.66(b)(3)(i) that disenrollment transactions be submitted within 15 days of receipt. Commenters pointed out that we do not process disenrollments every 15 days and suggested the requirement be modified to coincide with the 30-day requirement for enrollment transactions outlined at §422.60(d)(6).

Response: Our intent when establishing this requirement was to ensure that a beneficiary's choice to disenroll would be handled as expeditiously as possible. We are in the process of implementing a system that will be capable of processing these transactions more than once a month. However, we recognize that until the systems are modified, the requirement may not allow a sufficient amount of time to process a disenrollment action. Therefore, we have modified the regulations at §422.66(b)(3)(i) to state that the time frame to submit disenrollment transactions will be "specified by HCFA," and have made a conforming change at

§422.66(f)(2). This will give us the flexibility to make changes as system enhancements are developed in the future. For the time being, we are specifying that disenrollment transactions be submitted within the same time frame as enrollment transactions.

Comment: Several commenters asked that we provide additional clarification in §422.66(b)(5)(i) with respect to when an enrollment is not legally valid. Two of the commenters stated that we should clarify whether a lack of understanding would be included in the definition of a "legally valid enrollment," and whether it would result in a retroactive disenrollment. One commenter stated that we should clarify that an enrollment is not legally valid if it is determined at a later date that the individual did not meet eligibility requirements at the time of enrollment.

Response: There are a number of circumstances that would result in an enrollment not being considered “legally valid,” and we agree that the lack of understanding of plan rules (such as the “lock-in”) and ineligibility would be among these circumstances. However, a determination that an individual did not understand the terms of enrollment must be made on an individual basis. The criteria used in establishing evidence that an individual did not understand the terms of enrollment could include the following: continuing Medigap insurance coverage after receipt of the confirmation of enrollment letter from the M+C organization; an enrollment form signed by the member in situations where a legal representative should be signing for the member; enrolling in a supplemental insurance program immediately after enrolling in the M+C plan; or receiving nonemergency or nonurgent services out-of-plan immediately after the effective date of coverage under the plan. OPL 99.100 sets forth specific guidelines to assist M+C organizations when making determinations about lack of understanding and incorrect eligibility determinations.

Comment: One commenter asked for clarification of our process for approving retroactive disenrollments (either voluntary or involuntary) and the subsequent effective dates.

Response: Section 422.66(b)(5) describes retroactive disenrollments, which are disenrollments with a retroactive effective date in cases in which we determine that there was never a legally valid enrollment, or in which a valid request for disenrollment was properly made but not processed or acted upon. In cases of involuntary disenrollments, such as disenrollment for disruptive behavior or failure to pay premiums, the disenrollment actions are prospective and would not be retroactive. In cases in which we find that an enrollment was not legally valid, the disenrollment results in cancellation of the enrollment as of the effective date of the enrollment. Therefore, the effective dates for these retroactive disenrollments are based upon the effective dates for elections, as provided under §422.68. If the election subsequently found to be invalid was made during the annual election period in November, the effective date would be the first day of the following calendar year. If the election was made during an open enrollment period, the election would be effective the first day of the first calendar month following the month in which the election is made (or for elections made after the 10th day of a month, the first day of the 2nd calendar month following the date of the election). Effective dates for elections made during a special election period vary, dependent on the situation, and guidelines concerning these effective dates are provided in instructions to the M+C organizations. Elections made during special election periods for individuals age 65 would be effective the first day of the first calendar month following the month in which the election is made.

Comment: Section 422.66(d) states that an M+C organization must accept any eligible individual who is enrolled in a health plan offered by "an" M+C organization. One commenter stated that this section needs to clearly state that the M+C organization must accept any individual who is enrolled in a health plan offered by "the" M+C organization offering the other plan in which the individual is enrolled.

Response: We agree that the use of the term "an" could imply that the requirement applies to any organization, such that all M+C organizations must accept all eligible individuals enrolled in any commercial health plan offered by any M+C organization. In fact, our intent is for the requirement to apply to a specific M+C organization, namely the organization that offers both the commercial health plan in which the individual is enrolled and the M+C plan in which the individual will be enrolling. Therefore, we are revising §422.66(d)(1) to specify that a plan offered by an M+C organization must accept any eligible individual who is enrolled in a health plan offered by "the M+C organization."

Comment: One commenter believes there is a conflict between paragraphs (3) and (5) in §422.66(d). The commenter reads §422.66(d)(3) to provide that the individual will convert to the M+C plan unless he disenrolls, while §422.66(d)(5) provides that the individual must fill out an election form in order to convert.

Response: We do not agree that there is a conflict between the two sections of the regulation, but recognize that some clarification is desirable to prevent confusion. We are revising §422.66(d)(3) of the regulation to refer to the individual affirmatively choosing to remain enrolled with the organization as an M+C enrollee, and to state that conversion is effective the month of entitlement to both Medicare Part A and Part B "in accordance with the requirements in section §422.66(d)(5)." We also have deleted a reference in §422.66(e)(2) to an individual being “deemed” to have made an election, since this reference is inconsistent with the requirement in §422.66(d)(5) that an election form be completed and signed. These revisions will clarify that while we have established the effective date of coverage under §422.66(d)(3), the coverage may begin only if the individual completes and signs an election form, as required at §422.66(d)(5).

Comment: One commenter believes that §422.66(e)(2) (which states that an individual is considered to have continued an election in an M+C plan until the M+C plan is discontinued or no longer services the area in which the individual resides, and the organization does not offer or the individual does not elect the option of continuing enrollment) may be interpreted to absolve the M+C organization of any obligations when the person leaves the service area and has not selected a new health plan or original Medicare. The commenter suggested that the regulations should make clear that an individual who leaves his or her M+C plan service area is entitled to a special election period, as is the case when the M+C plan ceases to serve the service area.

Response: If an M+C plan enrollee leaves the plan's service area, but has not informed the M+C organization offering the plan of a permanent move, the M+C organization does have continued obligations to cover emergency and urgent services that must be covered out of area. Once the M+C organization is made aware of such a permanent move, the organization is obligated under §422.74(b)(2)(i) to disenroll the individual unless he or she has moved to a continuation area and requests to continue enrollment as a continuation area enrollee. With respect to the commenter's concern about a special election period being provided under these circumstances, §422.62(b)(2) clearly provides an M+C plan enrollee who moves out of his or her M+C plan service area with the same right to a special election period that the enrollee gets under §422.62(b)(1), cited by the commenter, in the case of an M+C plan termination.

Comment: One commenter was concerned about ensuring that all enrollees under a section 1876 risk contract--without regard to residence--be deemed to be enrollees of an M+C plan offered by the section 1876 contractor on January 1, 1999.

Response: We agree, and note that the interim final rule preamble states that we have interpreted the statute to allow an individual to transition from the section 1876 plan to an M+C plan "without regard to location of residence" (63 FR 34977). Our intent was to ensure that no individual enrolled in a section 1876 plan on December 31, 1998, would be adversely affected by the BBA changes, but instead would be able to maintain an established relationship with a Medicare contracting organization. Therefore, we clarified in the interim final rule that all individuals enrolled in a section 1876 plan on December 31, 1998 could convert to the corresponding M+C plan on January 1, 1999. We further clarified this "grandfathering policy" in OPL 99.084, dated February 26, 1999, which states that an individual who was enrolled in a section 1876 risk plan effective December 1, 1998 or earlier and remained with the risk plan on December 31, 1998, automatically continued to be enrolled in the M+C organization on January 1, 1999.

Comment: One commenter suggested that we include in the regulations text our operational policy recognizing State laws that govern who may sign election forms for beneficiaries. The commenter also believes we should clearly incorporate recognition of the State law, including health care consent laws.

Response: In general, and as previously discussed in the preamble of the June 26, 1998 interim final rule, we believe that the M+C-eligible individuals should personally complete and sign any election form or disenrollment request (referenced at §422.66(b)) whenever possible. We also recognize that there may be times that an individual is unable to sign for himself or herself. Laws governing who may sign a health insurance application vary from State to State. Therefore, while the regulations provide for the beneficiary to sign an election form, we defer to State laws (for example, laws governing the exercise of a power of attorney) on who may sign on behalf of a beneficiary where a beneficiary signature is required. We do not believe it is necessary to make provision for this in the regulations text, because where State law permits another individual to sign for a beneficiary with respect to health care decisions, this authority would extend to cases in which the beneficiary's signature is required under Medicare regulations.

Comment: Section 422.66(d)(1) states that an M+C plan offered by an M+C organization must accept any eligible individual who is enrolled in a health plan offered by an M+C organization during the month immediately preceding the month in which the individual is entitled to Medicare Part A and Part B. One commenter asked us to clarify whether the use of the term "health plan" refers only to fully insured products, or whether the term would include self-funded members.

Response: The term "health plan" in §422.66(d)(1) refers to any commercial health plan that the M+C organization offers. This may include fully insured products, self-funded products, and indemnity products.

8. Effective Dates of Coverage and Change of Coverage (§422.68)

An election made during an initial coverage election period as described in §422.62(a)(1) is effective as of the first day of the month of entitlement to both Part A and Part B. Also, for an election or change of election made during an annual election period as described in §422.62(a)(2), coverage is effective as of the first day of the following calendar year. For an election or change of election made during the open enrollment periods described in §422.62(a)(3) through (a)(6), coverage is effective as of the first day of the first calendar month following the month in which the election is made (except that if the election or change of election is made after the 10th day of a calendar month, the election takes effect on the first day of the second calendar month after the date of the election.)

For an election or change of election made during a special election period as described in §422.62(b), we determine the effective date of coverage, to the extent practicable, in a manner consistent with protecting the continuity of health benefits coverage. For an election of coverage under original Medicare made during a special election period for an individual age 65 as described in §422.62(c), coverage is effective as of the first day of the first calendar month following the month in which the election is made.

<u>Comment</u>: Several commenters objected to the effective date in the interim final rule for elections made during open enrollment periods, which was the first day of the month after the month the election is received. The commenters believe this effective date did not allow enough time to process the enrollment. They believed that this deadline would result in increased retroactive transactions and would be burdensome on M+C

organizations. Commenters also expressed significant concerns over liability and access to services if Medicare entitlement is not verified expeditiously. Commenters also noted the need for us to make system changes to accommodate the new effective date requirements, and to clarify how we intend to implement the requirements with respect to M+C organization submission of data. The commenters recommended the effective dates be as they were under section 1876 of the Act which, under §417.450(a)(2), may not be earlier than the first month after, nor later than the third month after, the month in which we receive the information necessary to include the beneficiary as a Medicare enrollee of the HMO or CMP in our records.

Response: Section 1851(f) of the Act supersedes all prior section 1876 requirements and specifically delineates the effective dates for elections made in the M+C program. Consistent with the changes to section 1851(f) of the Act made by section 502 of the BBRA, we are revising §422.68(c) to provide that coverage is effective either on the first day of the calendar month after the date of an election or change of election or, for elections or changes of election made after the 10th day of a calendar month, on the first day of the second calendar month after the date of the election or change of election. In addition, based on our authority to establish requirements that can reduce the potential for retroactive transactions, we have developed guidelines for M+C organizations that include requirements for M+C organization verification of Medicare entitlement before submission of enrollment data (see OPL 99.100). The verification policy should minimize the potential for retroactive enrollment situations. Additionally, the new effective dates outlined in section 1851(f) of the Act have resulted in the need to clarify a number of operational issues. While the expansion of managed care provisions under the BBA has presented an extraordinary challenge to us, we have successfully implemented the necessary systems requirements to support this change in effective dates. Additionally, we have issued other guidelines to M+C organizations (OPL 98.074, our November 17, 1999 Systems Informational Letter, and OPL 2000.113) that outline how to identify the correct effective date and process the enrollments through our systems.

Comment: Several commenters were concerned that the new effective date requirements will not allow the M+C organization to receive our confirmation of the enrollment before the effective date, which could in turn increase beneficiary confusion.

Response: Section 1851(f) of the Act clearly outlines the effective dates of enrollment in M+C plans. If an eligible individual has elected an M+C plan, the M+C organization must cover the individual beginning on the effective date of coverage, even if the organization has not yet received final confirmation from us. An M+C organization can take several actions to reduce the chance of beneficiary confusion, including verifying Medicare entitlement before submission of enrollment data to us. This should increase the likelihood that we will confirm the individual's enrollment.

Comment: One commenter stated that original Medicare should pay M+C organizations for services furnished to individuals for whom retroactive disenrollments were processed.

Response: If a retroactive disenrollment is processed for a beneficiary, the M+C organization in which the beneficiary was enrolled can always bill for Medicare covered services rendered to the beneficiary.

Comment: One commenter stated that the effective date of coverage for individuals who enroll during an open enrollment period (the first day of the first calendar month following the month the election is made) is too rigid, and that delayed effective dates should be permitted.

Response: Again, section 501(b) of the BBRA provided for some relief in this regard by changing the effective dates for elections or changes in election made after the 10th day of a month. We also note that we have the authority under section 1851(f)(4) of the Act to establish effective dates for individuals who meet the condition for special election periods.

We have provided for prospective effective dates for individuals electing benefits through their employer group health plans, and published this guidance on April 20, 1999 in OPL 99.087. We provided additional guidance on the effective dates of coverage for other special election periods authorized under §422.62(b) in OPLs 99.098 and 99.100.

Comment: Two commenters questioned how M+C organizations will be expected to handle multiple transactions, given the new effective date requirements.

Response: As stated at §422.50(b), an individual may not be enrolled in more than one M+C plan at any given time. Nevertheless, there are times when an individual will try to elect more than one plan for the same effective date, and it is not always clear with which plan the individual truly intends to be enrolled. On August 9, 1999, we issued OPL 99.100, which includes guidelines on what actions an M+C organization must take in the event of a multiple transaction in order to determine with which M+C plan the beneficiary should be enrolled.

Comment: One commenter stated that we should establish performance standards that take into account difficulties that we and M+C organizations will have in meeting effective date requirements.

Response: We recognize that section 1851 of the Act has resulted in significant changes to the Medicare program and that

M+C organizations need time to prepare for the changes. We have provided additional guidance on implementation of M+C entitlement, eligibility, and elections to M+C organizations through various OPLs (98.072, 98.073, 99.083, 99.084, 99.087, 99.098, 99.100, 99.104, 99.105, 99.109, and 2000.113) and a November 17, 1998 Systems Informational Letter. These letters outline how to identify the correct effective date, how to process enrollments with the new effective dates, how to transition from section 1876 to M+C enrollment and disenrollment rules, and when grandfathered members must be disenrolled from M+C plans. As a result, we believe we have given adequate time to modify operations and systems to implement the new M+C program. In addition, we continue to develop guidelines for M+C organizations on M+C entitlement, eligibility, and elections to M+C organizations. Any monitoring of performance will take into account the time M+C organizations have needed to implement the new program.

9. Disenrollment by the M+C Organization (§422.74)

The general rule for disenrollment by the M+C organization is that an M+C organization may not disenroll an individual from any M+C plan it offers; or request or encourage (orally or in writing, or by any action or inaction) an individual to disenroll. However, §422.74(b) describes the conditions under which the M+C organization may either be permitted or required to disenroll an individual. Under §422.74(b)(1), the M+C organization may choose to disenroll an individual based on that individual's (1) failure to pay premiums, (2) disruptive behavior, (3) provision of fraudulent information on his or her election form, or (4) having permitted his or her enrollment card to be abused. Section 422.74(b)(2) requires the M+C organization to disenroll the individual if the individual no longer resides in the M+C plan's service area, the individual loses entitlement to Medicare Part A or Part B benefits, or the individual dies. The M+C organization must follow the procedures specified at §422.74(c) and (d) when disenrolling an individual. The procedures to be followed and the consequences of the disenrollment vary depending upon the cause of the disenrollment.

Comment: One commenter believes that the 90-day grace period that must be afforded to an enrollee before a disenrollment for nonpayment of premium could be financially burdensome in 1999 since ACRs that did not necessarily reflect these costs were filed before the M+C regulations were published.

Response: We recognize that 1999 was a transition year with many new requirements. With respect to 2000, however, M+C organizations were fully aware of all regulatory requirements before filing their ACRs.

Comment: Several commenters believed that the 90-day grace period for nonpayment of premiums is too long. Two commenters recommended a 30-day grace period rather than the 90-day grace period. They noted that if an organization has to wait 90 days before disenrolling an individual, this potentially results in 4 months without the organization receiving payment, since organizations do not send notice to beneficiaries until the beginning of the month after payment is due. One commenter recommended that grace period extend until the last day of the third month following the date payment is due.

Response: Section 1851(g)(3)(B)(i) of the Act requires us to provide for a "grace period" before enrollment can be terminated for nonpayment of premiums. In determining the grace period, we adopted the grace period that Congress provided for in section 1836(b)(2) of the Act with respect to a termination for nonpayment of premiums for Supplementary Medical Insurance Benefits for the Aged and Disabled (that is, Part B). This results in consistent standards between the M+C program and the original Medicare program.

Comment: Several commenters believe that M+C organizations should be permitted to allow an enrollee to remain enrolled and eliminate only optional benefits if a member fails to pay premiums charged for such optional benefits. Some commenters believe that the option to disenroll for nonpayment of premiums implied that an organization could only disenroll the beneficiary from the plan, and could not simply eliminate the optional benefits. One commenter questioned whether under our rules, it might be necessary to disenroll the individual and re-enroll them as a "standard option" enrollee to accomplish this.

Response: We agree that providing the M+C organizations the option to retain an enrollee while eliminating an optional benefit for which premiums are not paid is a desirable and appropriate means of promoting continuity of care for beneficiaries. We are adding a provision to §422.74(d)(1)(iv) that expressly provides an M+C organization the option to discontinue an optional supplemental benefit for which premiums are not paid, while retaining the beneficiary as an M+C enrollee.

Such an action would not affect the beneficiary's status as a member of the M+C plan, and would not constitute a new election. Therefore, the M+C organization does not have to formally disenroll and re-enroll the individual when downgrading the member's enrollment to the standard benefit package because the beneficiary fails to pay the plan premiums.

Comment: One commenter recommended that the M+C organization should be required to send notice to enrollees that premium payment is overdue within 10 days, rather than 20 days. Another commenter supported the 20-day time frame.

Response: Section 1856(b)(2) of the Act provides for the use of standards established under section 1876 to implement analogous provisions of the M+C statute when those standards are consistent with standards established in the BBA for the M+C program. Section 417.460(c)(1)(iii) requires section 1876 contractors to send notices of disenrollment for nonpayment of premiums to the enrollee before it notifies us. In addition, §417.460(c)(1)(i) requires that the contractor demonstrate to us that it made reasonable efforts to collect the unpaid amount. Section 422.74(d)(1) of the M+C regulations carries over both of these requirements and clarifies that "reasonable efforts" include sending a notice of nonpayment to the beneficiary within 20 days after the date the payment was due. The notice advises the beneficiary that he or she has 90 days from the date of the notice to provide payment. We continue to support this policy and believe that 20 days is a reasonable maximum time frame within which to make an effort to collect unpaid premiums. We note that an M+C organization may notify the individual as soon as the premium payments are past due (that is, send a notice before 20 days have passed), in which case the 90-day grace period would begin on the day the M+C organization sends the notice.

Comment: One commenter requested clarification of the effective date of disenrollments for nonpayment of premiums following the 90-day grace period. The commenter asked that we clarify for how long the organization is obligated to provide benefits and we will continue to pay capitation.

Response: The effective date of disenrollment for nonpayment of premiums is the first day of the month after the 90-day grace period ends. The M+C organization must continue to provide benefits and we will continue to pay capitation until the disenrollment is effective. We clarified this policy in OPL 99.100, issued on August 9, 1999. We note that §422.74(d)(1) erroneously refers to the possibility of disenrollment for an individual who fails to pay any "basic or supplementary premiums." Section 1851(g)(3)(B)(i) of the Act refers to "basic and supplementary premiums" and we are revising the regulations accordingly.

Comment: Two commenters requested clarification regarding the standards for disenrollment for disruptive behavior under the Health Insurance Portability and Accountability Act (HIPAA) and BBA, unsure if the two statutes were in conflict in this area.

Response: For any issues for which there is a perceived conflict in the disenrollment standards established under the BBA (or the BBRA) and those established under HIPAA, the BBA standards (that is, the standards in §422.74 pursuant to section 1851(e) of the Act) would control for M+C purposes.

Comment: One commenter recommended that disenrollments for fraud and abuse should include other fraudulent activities related to the delivery of health services, such as visiting multiple doctors for the purpose of obtaining specific drugs and/or using another enrollee's membership card when benefits have been exhausted.

Response: As noted above, section 1856(b)(2) of the Act provides for the use of section 1876 standards to implement analogous provisions of the M+C statute when those standards are consistent with standards established in the BBA for the M+C program. The regulations in section 1876 of the Act addressing disenrollments for fraud and abuse at §417.460(d) have been largely adopted in §422.74(d)(3), which permits disenrollment of a beneficiary for providing fraudulent information that affects eligibility to enroll or for permitting others to use his or her enrollment card to obtain services. Manual instructions implementing §417.460(d) further clarified that any abuse relating to a membership card was included as a ground for disenrollment. Thus, using another member's card would constitute grounds for disenrollment, just as would loaning someone else a card. With respect to the commenter's other example about multiple visits to physicians to obtain drugs, an M+C organization's utilization review system should be able to identify these abuses.

Comment: One commenter requested that we add clarification regarding when a disenrollment is effective in cases of fraudulent behavior.

Response: Disenrollment of an individual who has committed fraud or who permits the abuse of his/her enrollment card is effective the first day of the calendar month after the month in which the M+C organization gives the member the written notice of his/her termination.

Comment: One commenter is concerned that our process for making disenrollment decisions related to disruptive behavior would result in numerous retroactive disenrollment situations. The commenter suggested that we clarify or revise the regulation to assure that any effective dates for disenrollment be prospective in situations where an individual is being disenrolled for disruptive behavior.

Response: Section 422.74(d)(2)(v) establishes procedures for our review of an M+C organization's proposed disenrollment of an individual for disruptive behavior. Under these procedures, we review documentation submitted by the M+C organization within 20 working days, and notify the organization within 5 working days of whether it may disenroll the individual. Section 422.74(d)(2)(vi) then states that if we permit the disenrollment for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the M+C organization gives the individual written notice of the disenrollment. Since these procedures do not allow an M+C organization to disenroll an individual for disruptive behavior until after we have approved the disenrollment, we believe the process provides only for prospective disenrollments.

Comment: Several commenters believe that 12 months is too long to wait before disenrolling an individual for being permanently out of the service area. Many commenters are concerned that the beneficiary will be able to receive only urgent and emergency care during this time, and that 12 months is too long without routine and coordinated care. They made several recommendations. One commenter recommended that 6 months would be reasonable to cover those individuals who live in different parts of the country during the year, while still maintaining contact with the primary care physician for preventive care. Two commenters recommended maintaining past policy of disenrollment of members that move outside of service area for more than 90 days, unless the plan has an affiliate. Another commenter also supported a return to a 3-month time frame. One commenter requested clarification regarding the requirements for disenrolling members from M+C organizations if they move permanently before the 12 months have expired. The commenter believes that if the request to disenroll was written or other acceptable evidence was presented, the M+C organization may disenroll the individual from the plan.

Response: We must first clarify that if an M+C organization determines that an individual has permanently left the service area of the M+C plan, it must disenroll the individual from that plan regardless of whether 12 months have passed, unless the individual chooses a continuation of enrollment option. This is outlined at §§422.74(b)(2)(i) and 422.74(d)(4). However, we believe that this point may not be entirely clear in the existing regulations and thus we are revising §422.74(d) to specify that an individual who has "permanently" moved out of a plan's service area must be disenrolled. Note that this disenrollment requirement also applies to individuals who are enrolled in a plan under the expanded seamless conversion option for former commercial plan enrollees that is now set forth at §§422.50(a)(3)(ii) and (a)(4). That is, should the individual change his or her residence, he or she would be treated the same as any other enrollee who moves to a residence outside of the service area.

The 12-month rule set forth under existing §422.74(d)(4) establishes the time limit for how long an individual who has left the service area on a temporary basis may remain a member of the M+C plan. That is, an M+C organization must disenroll an individual who has not permanently changed his or her address but has been out of the service area for over 12 months.

After considering the comments on this provision, we agree that 12 months is too long for a beneficiary to have access only to emergency and urgently needed care (based on our operational policy that when a member is out of the service area, the M+C organization is required to cover only emergency and urgently needed care). Therefore, we are further revising §422.74(d)(4) to state that the M+C organization must disenroll an individual, unless he or she chooses the continuation option, if the individual leaves the plan's service area on a nonpermanent basis for over 6 months. This change is within the parameters of the previous requirement under section 1876 of the Act which, as provided in §417.460(f)(2), allowed an uninterrupted absence from the geographic area for more than 90 days but less than 1 year. However, we believe it is appropriate to extend the time frame from 90 days to 6 months to accommodate the many beneficiaries who leave the service area for seasonal periods each year, which often last more than 90 days, but rarely more than 6 months.

We note that on August 9, 1999, we issued OPL 99.100, specifying that: (1) if an M+C organization receives notice of a permanent change of address from the member (or member’s legal representative) at any time, then it must disenroll that individual from the plan if that change of address is outside the M+C plan's service area unless the member chooses the continuation of enrollment option; and (2) if a member leaves the service area of the plan, then the M+C organization must disenroll the member if the absence extends beyond 12 months (now, 6 months).

Comment: One commenter asked whether an M+C plan can provide out-of-area coverage in excess of that required by Medicare for only part of the 12-month period when a member is out of the M+C plan's service area.

Response: We allow M+C organizations the flexibility to develop programs to continue benefits for those members who temporarily leave the service area. We have developed operational policies regarding visitor programs. Again, note that revised §422.74(d)(4) requires an M+C organization to disenroll an individual, unless he or she chooses the continuation option, if the individual moves out of the plan's service area, for over 6 months.

Comment: One commenter asked for clarification of the effective date when an individual is disenrolled for being out of the area for over 12 months.

Response: Consistent with the change in §422.74(d)(4), the effective date of disenrollment if a member is out of the area and has not informed the M+C organization that the move is permanent will be the first day of the calendar month after the 6 months has passed, and after appropriate written notice has been provided to the member. If the M+C organization is made aware of a permanent move out of the service area, disenrollment is effective the first day of the calendar month after the date the member begins residing outside of the M+C plan's service area, and after written notice has been provided to the member.

Comment: One commenter recommended that §422.74(d)(7), which provides for disenrollment when a plan terminates services in the area in which the enrollee resides, explicitly states that disenrollment is automatic in this case.

Response: The effective date of a disenrollment based on an M+C plan termination or reduction in service area is the date that the M+C plan termination is effective, and disenrollment is automatic. Beneficiaries would have already received advance notice of such a termination as part of the nonrenewal requirements in §422.506(a)(2). Accordingly, we have revised §422.74(d)(7)(ii) to reference the time frames in §422.506(a)(2).

Comment: One commenter recommended that notices for involuntary disenrollments should be mailed to individuals authorized to make elections on behalf of an enrollee as well as the enrollee.

Response: In general, and as indicated by our requirement that the beneficiary complete and sign the M+C enrollment form, we believe that an M+C-eligible individual should personally complete and sign any election form or disenrollment request whenever possible. If for some reason a beneficiary is unable to sign the election form and needs a surrogate, we defer to State law on who may sign for other persons. Legal representatives of such individuals who authorize the election of an individual must also sign the election form and specify their relationship with the enrollee. In instances of involuntary disenrollment, notifications of disenrollment occur before any action is taken, to ensure that the individual has adequate time to review his or her health care options. Since the legal representative has identified him/herself to the M+C organization, the M+C organization should ensure that both the legal representative and the enrollee subsequently receive, in a timely manner, any important information provided by the M+C organization related to the health care decisions of the beneficiary.

Comment: One commenter is concerned that the time frames for our review of an M+C organization's proposed disenrollment for disruptive behavior (20 working days for a determination and the subsequent 5 days to notify the M+C organization) are too long. The commenter believes that 5 days is reasonable for us to make our determination.

Response: Again, section 1856(b)(2) of the Act provides for the use of section 1876 standards to implement analogous provisions of the M+C statute when those standards are consistent with standards established in the BBA for the M+C program. Regulations at §417.460(e)(5), which set forth the requirements for our review of an HMO's or CMP's proposed disenrollment for cause, addressed this issue. Under §417.460(e)(5)(ii), we make this decision within 20 working days after receipt of the documentation material and notify the HMO or CMP within 5 working days after making our decision. We see no reason not to retain this standard under the M+C program, and have done so in §422.74(d)(2)(v)(B). We believe that this period of time ensures that we can conduct a thorough review of all documentation submitted by the M+C organization and the beneficiary.

Comment: With respect to an M+C organization termination of an enrollee for disruptive behavior, one commenter asked for clarification of the process. For example, the commenter wanted to know who makes the determination, what appeal rights the beneficiary has, the time frame for a determination, and whether the beneficiary stays in the plan during the review of a determination. The commenter also asked if there is a possibility of coverage days lost while we are making the decision, and whether premiums would be refunded if the beneficiary is disenrolled.

Response: The M+C organization must make a serious effort to resolve the problems presented by the beneficiary, which includes the use of the M+C organization's grievance procedures. The M+C organization must notify the beneficiary of its intent to request such a disenrollment, as well as the beneficiary's rights under the M+C organization's grievance procedures. As described above, the final decision regarding the determination of disruptive behavior is made by us, as provided by §422.74(d)(2)(v), which outlines our review authority of the M+C organization's proposed disenrollment. After reviewing the documentation submitted by the M+C organization and any information submitted by the beneficiary, we decide whether the M+C organization has met the disenrollment requirements. Until the disenrollment is effective, the beneficiary will continue to receive services from the M+C organization. Any premiums or other charges paid for coverage after the effective date would be refunded to the beneficiary; however, the beneficiary would be liable for the original Medicare cost-sharing and permitted balance billing in the case of any Medicare covered services provided by the M+C organization after the effective date of the disenrollment.

Comment: One commenter requested clarification regarding when to send out notices for disenrollments for cause.

Response: The basic requirement for notices is provided at §422.74(c), which states that for any optional or required disenrollment (other than death or loss of entitlement), the organization must give the individual written notice of the disenrollment with an explanation of why the M+C organization is planning to disenroll. The notice must be mailed to the individual before submission of the disenrollment notice to us. Please note that we have amended §§422.74(c)(1) and (c)(2) to clarify that these notice provisions do not apply for disenrollments resulting from plan terminations or reduction of service or continuation areas, since there are no grievance rights provided in these situations. The notice requirements for plan termination are outlined in §§422.74(d)(7) and 422.506(a)(2).

Comment: One commenter noted that §422.74 only provides the opportunity for an individual to express a grievance to the M+C organization for an enrollment or disenrollment decision. The commenter believes that we should allow these decisions to be appealed because such decisions should not be left to the M+C organization.

Response: We agree with the commenter that decisions to disenroll for fraud or disruptive behavior should not be left solely to the M+C organization, which is why the regulations, at §§422.74(d)(2)(iv) and (3)(iii) provide for our role in these cases. However, in other cases, we believe that beneficiaries will be well-protected from a potentially wrongful disenrollment by the internal grievance procedures of the M+C organization. An M+C organization's decision to disenroll an individual does not meet the regulatory definition of an organization determination and thus, by definition, is not an issue that is eligible for the M+C reconsideration process.

10. Approval of Marketing Materials and Election Forms (§422.80)

Section 1851(h) of the Act outlines the requirements related to marketing by M+C organizations. These provisions are implemented in §422.80 of the interim final rule. Section 422.80(a) implements the requirements in section 1851(h)(1) that all marketing material and application forms be submitted to us for approval 45 days before distribution, and that such materials may be used only if we do not disapprove such use by the end of the 45-day period. Section 422.80(b) defines the "marketing materials" that must be submitted for approval. We note that we have made a minor revision to this regulation to reflect the fact that HCFA does not review newsletters as marketing material. The reference to newsletters was included in the interim final rule because it appeared in the part 417 regulations governing marketing by section 1876 contractors. In fact, HCFA did not treat newsletters as marketing materials in the case of section 1876 contractors, and there was no intent in the interim final rule to change HCFA's practice on this point. The interim final rule thus should not have included the reference to newsletters, and we are correcting our error in doing so.

Section 1851(h)(2) of the Act requires that the M+C standards include guidelines for review of marketing materials and requires that the guidelines provide that the Secretary will not approve materials that are inaccurate or misleading. Section 422.80(c) establishes the guidelines for our review of marketing materials. Consistent with the provision in section 1856(b)(2) of the Act for use of existing section 1876 standards, the guidelines in §422.80(c) include existing marketing guidelines for HMOs and CMPs (from §417.428), which have been in effect since the inception of the Medicare risk contract program.

Section 1851(h)(3) of the Act provides that if we have not disapproved the dissemination of marketing materials or forms with respect to an M+C plan in an area, we are deemed not to have disapproved the distribution in all other areas covered by the M+C plan and M+C organization except with regard to any portion of the material or form that is specific to the particular area. This "deemed approval" or "one-stop shopping" provision is implemented in §422.80(d).

Section 1851(h)(4) of the Act provides that M+C organizations shall conform to "fair marketing standards" and requires that the fair marketing standards prohibit organizations from providing cash or other monetary inducements for enrollment. Section 422.80(e) outlines the fair marketing standards provided for under section 1851(h)(4) of the Act, and includes existing section 1876 standards as provided for in section 1856(b)(2) of the Act.

Finally, §422.80(f) specifies that we may permit M+C organizations to develop and distribute marketing materials specifically designed for members of an employer group who are eligible for employer-sponsored benefits through the M+C organization. Although these materials must be submitted for approval under §422.80(a), we do not review portions of these materials that relate only to employer group benefits, rather than to M+C plan benefits.

The public comments that addressed marketing issues governed by §422.80 are discussed below.

Comment: Two commenters suggested that we consider lengthening the review and approval processing time for marketing material from 45 days to either 60 or 90 days. The commenters believe that we need additional time to perform adequate review of marketing material submitted by M+C organizations. Another commenter suggested that the processing time be reduced to 14 days and the deemed approval time period be 30 days. The commenter asserted that M+C contractors must complete obligations within 14-30 days; therefore, we should be held to the same standard. The commenter also stated that 45 days for approval of marketing material is too long for effective marketing or to correct misinformation in the press.

Response: As noted above, section 1851(h)(1) of the Act establishes a 45-day limit for our review and approval of marketing materials. That is, absent our disapproval of such materials, the statute permits an M+C organization to distribute marketing materials 45 days after submitting the materials for review. Since any materials that are not affirmatively "disapproved" are effectively "approved" for distribution, we recognize the importance of completing our review of all marketing materials within 45 days. Accordingly, we are evaluating our marketing review procedures to identify ways we can promote greater efficiency in the marketing review process. We do not believe that reducing the marketing review and deemed approval periods would allow our staff adequate time to ensure that marketing material is accurate and not misleading to potential enrollees and beneficiaries.

Comment: Many commenters expressed concern regarding inconsistent review and treatment of marketing material by our different regional offices. A few commenters recommended that we consider centralized review of marketing material to promote greater consistency across the regions and central office. Several commenters also suggested that we require standard language and at a minimum, 12-point print, in all M+C marketing materials.

Response: We understand the concerns of M+C organizations regarding uniform application of marketing review and guidelines. To address these concerns, we have convened a team of representatives from our 10 regional offices and our central office that is responsible for addressing marketing issues which arise in policy and operationally. We recognize that centralized review may promote more consistent application of marketing review policy, and we are currently evaluating the feasibility of such review. Although we want to provide M+C organizations with the flexibility to develop marketing material that will distinguish their products and services from other organizations, we also believe that standardizing M+C marketing materials will facilitate beneficiary use and choice. Thus, we have taken steps to standardize beneficiary materials. Pursuant to our authority under §422.80(c)(1) to require the use of “a format. . .and. . .standard terminology. . .specified by HCFA,” we required M+C organizations to use a standardized Summary of Benefits format in describing their 2000 benefits, beginning in the fall of 1999. This Summary of Benefits provides beneficiaries with information on M+C plans that is standardized in terms of format, language, and content. We also plan to identify other beneficiary notification materials for which standardization will be required. The current marketing guide already directs M+C organizations to use 12-point print. M+C organizations can obtain the marketing guide from our website (www.hcfa.gov).

Comment: One commenter suggested that we clarify that documents developed by pharmacies to conduct pharmacy compliance programs are not marketing and promotional materials. Another commenter recommended that we clarify that marketing materials intended to promote the M+C organization (distinct from its

Medicare contracting function) should not be subject to the marketing review process.

Response: To the extent that "pharmacy compliance" documents are directly related to health care or quality, we do not review them as marketing materials. On the other hand, if the "pharmacy compliance" materials are used to market the program in pre-enrollment marketing materials and advertisements, we treat them as marketing materials subject to our review and verification.

We do not review materials that are directed solely at an HMO’s commercial population. However, we believe that any materials targeted at the Medicare population, and designed to inform beneficiaries about benefits, or encourage beneficiaries to enroll or remain enrolled, should be subject to our review on their behalf. Thus, we are retaining the provision under §422.80(b)(1) that calls for review of materials that "promote the M+C organization."

Comment: A few commenters, particularly those providing services in rural areas, urged that we require M+C organizations to include a list of subcontracted providers in their pre-enrollment marketing material. Others suggested that we require organizations to include a list of participating providers in their marketing materials.

Response: We understand that provider directories are generally available at sales presentations or when a beneficiary visits the M+C organization. Thus, we do not think it is necessary or appropriate to mandate that an M+C organization identify subcontractors or furnish provider directories in general marketing materials or sales kits. We note that §422.80(c)(1) directs M+C organizations to provide Medicare beneficiaries interested in enrolling in an M+C plan with a written description of plan rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges. M+C organizations also must meet the detailed disclosure requirements outlined in §422.111, which include informing enrollees of the "number, mix, and distribution (addresses)" of available providers. We believe that these requirements adequately address beneficiary information needs.

Comment: Several commenters requested that we define "significant non-English speaking population." One commenter recommended that 5 percent of the Medicare-eligible population be the standard, while another recommended a standard of 25 percent.

Response: Section 422.80(c)(5) of the interim final regulation requires, for markets with a significant non-English speaking population, that M+C organizations provide marketing materials in the language of these individuals. The term "significant" can refer to either the number or percentage of the affected population. We note that the Office for Civil Rights within the Department of Health and Human Services is responsible for implementing standards and providing guidance concerning the obligations of Federal fund recipients (such as M+C organizations) to provide language assistance to individuals who have limited English proficiency. As more information becomes available to HCFA, we will provide further guidance on M+C organizations' responsibility in this regard.

Comment: Some commenters asked that we clarify the role of physicians in the marketing of M+C products to their patients. The commenters also requested further guidance regarding whether physicians are allowed to counsel patients about their health insurance choices. Commenters both supported and opposed allowing physicians to advise potential enrollees and beneficiaries about M+C plan options.

Response: We agree that the role of physicians should be clarified. Accordingly, we are amending the standards for marketing to add a new §422.80(e)(1)(vi) that permits provider groups and individual providers to distribute health plan brochures (exclusive of applications) at a health fair or in their own offices. Physicians may discuss, in response to an individual patient's inquiry, the various benefits in different health plans. While this discussion is entirely appropriate within the doctor-patient relationship, M+C organizations may not use providers/provider groups to distribute printed information comparing the benefits of different health plans, unless the materials have the concurrence of all organizations involved and have received prior approval from us. Physicians and other providers may not accept plan applications. We also are adding a new §422.80(e)(1)(vii) that prohibits M+C organization representatives from accepting applications in provider offices or other places where health care is delivered.

Comment: One commenter recommended that we revise §422.80(c)(4) to reflect a statutory reference in section 1851(h)(2) of the Act to marketing material that is "materially inaccurate or misleading or...makes a material misrepresentation." The commenter believed that the omission of the term "material" creates a more stringent standard of review than that intended by Congress.

Response: We concur with this recommendation. As noted, section 1851(h)(2) states that "the Secretary shall disapprove...such material or form if the material or form is materially inaccurate or misleading or otherwise makes a material misrepresentation." Therefore, we are modifying §422.80(c)(4) to read as follows: "In reviewing marketing material or election forms under paragraph (a) of this section, HCFA determines that the marketing materials: ....(4) are not materially inaccurate or misleading or otherwise make material misrepresentations." This language is more consistent with the standard outlined in the statute, and we believe it can help avoid delays in the review and approval of marketing materials for immaterial or irrelevant errors.

Comment: Commenters also requested further guidance regarding the permissibility of offering "value-added services" to beneficiaries.

Response: In general, "value-added items and services" (VAIS) are items or services offered to beneficiaries by an M+C organization that do not meet the definition of a benefit as stated in §422.2; that is, benefits are health care services for which the M+C organization incurs a cost under the M+C plan that are submitted and approved through the ACR process. Examples of VAIS may include but are not limited to discounts in restaurants, stores, entertainment, or travel; they could also include discounts on health club memberships and on insurance policy premiums.

Because VAIS do not constitute a benefit under the M+C program, neither the actual costs of the VAIS nor associated administrative costs may appear in the ACR, nor are they subject to the Medicare appeals process. Nonetheless, VAIS may be of value to some enrollees, and we do not wish to deprive M+C enrollees of access to items and services commonly available to commercial enrollees. Therefore, M+C organizations may offer VAIS to Medicare enrollees, but materials describing VAIS must clearly distinguish between VAIS and M+C benefits, including clarifying that VAIS are not subject to the M+C appeal procedures. VAIS may not appear in the Beneficiary Information Form or the Plan Benefit Package. Further, VAIS may not be described in Medicare Compare, the Medicare and You handbook, or the Standardized Summary of Benefits. We will provide further guidance regarding VAIS in a forthcoming OPL.

Comment: One commenter inquired if the prohibition of monetary rebates to induce enrollment applies to the distribution of coupons.

Response: Cash or monetary rebates, including coupons that have more than a nominal cash value (if converted to cash) are prohibited under §422.80(e)(1)(i). This prohibition does not apply to items of nominal value ($10 or less). The coupons, or the combined value of the coupons, must not exceed the nominal value standard. Coupons that offer discounts on premiums or copayments are not permitted, because they would violate the "uniform premium" provisions of the statute, as outlined in §422.304. If coupons are for VAIS in excess of nominal value, they cannot be distributed or advertised pre-enrollment. However, these coupons may be used after enrollment.

Comment: Commenters objected to the fact that the regulations are silent regarding the consequences if an M+C organization violates the marketing standards. Two commenters recommended that we begin retrospective review of marketing materials, and pull the advertising campaign for those found to be egregiously inaccurate. Similarly, another commenter suggested that we nonrenew or terminate contracts with organizations that are substantially out of compliance with the marketing regulations.

Response: We recognize that marketing material distributed by M+C organizations must be accurate and not misleading to potential enrollees, and that M+C organizations should be subject to sanction for a substantial failure to comply with marketing rules. We accordingly are adding a new §422.510(a)(12) to specify that a substantial failure to comply with marketing guidelines is a ground for termination, and thus also a ground for nonrenewal or intermediate sanction (consistent with §§422.506(b)(1)(iii) and 422.572(b)).

Comment: Several commenters requested that we provide additional guidance regarding the documentation necessary to demonstrate that marketing resources are allocated for marketing to both the disabled and beneficiaries age 65 and over.

Response: Section 422.80(e)(2)(i) requires M+C organizations to demonstrate to our satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over. We plan to issue further guidance on this issue but, until then, we expect organizations to adopt their own procedures to implement these provisions. As a starting point, organizations may consider developing a formal marketing strategy that considers the needs of persons with disabilities and consulting with disability advocacy groups and outreach programs. We expect M+C organizations to avoid developing plans that could discourage the enrollment of persons with disabilities through the imposition of unusually large cost-sharing requirements for items and services frequently used by the disabled. M+C organizations are also expected to make their marketing materials accessible to persons with disabilities (including, for example, through use of alternative formats), and to establish mechanisms for making their marketing sessions accessible to the disabled Medicare population. Also, as discussed further in section II.C of this preamble, M+C organizations must comply with other applicable Federal statutes, including the Americans with Disabilities Act.

Comment: One commenter recommended that we revise or delete the heading "Employer Group Retiree Marketing" in §422.80(f) to reflect marketing to Medicare-eligible employees of the employer.

Response: We believe that "Employer Group Retiree Marketing" is an appropriate heading. This provision addresses only marketing materials geared toward retirees of an employer group that reflect non-Medicare benefits offered to group members by that employer. These retirees generally would include individuals who have retired based on a disability rather than age. Thus, a reference to “retirees” is not necessarily limited to the over-65 Medicare market. Moreover, this provision in no way limits an M+C’s obligation to market to both disabled and over-65 beneficiaries, both in a retiree group and otherwise.

Comment: Some commenters requested further clarification regarding the review of marketing material developed by employers for purposes of employer group marketing. One commenter inquired whether we will definitely permit M+C organizations to develop marketing materials for employer groups. Presently, §422.80(f) states that we "may" permit M+C organizations to develop marketing materials for employer groups.

Response: Although we will not review all the specific benefits offered by the employer group, we will review those items that fall within the disclosure requirements of §422.111. Further, we agree that the wording of §422.80(f) may be unclear; thus we are revising the regulation to: (1) specify that M+C organizations are permitted to develop marketing materials for employer groups; and (2) clarify that we will not review those portions of such marketing materials that relate solely to employer group benefits.

Comment: One commenter questioned whether it is appropriate to allow the term "senior" or the number "65" to appear in the name of an M+C plan. The commenter stated that including these terms could discourage some beneficiaries from enrolling in a particular M+C plan.

Response: We recognize that certain plan names may discourage enrollment by disabled beneficiaries. Accordingly, pursuant to our authority under section 1851(h)(4) of the Act to establish marketing standards, we have added a new §422.80(e)(1)(viii) that will prohibit M+C plan names that suggest that a plan is available only to Medicare beneficiaries age 65 or over, rather than to all beneficiaries. This prohibition generally bars plan names involving terms such as "seniors," "65+," etc. In fairness to M+C organizations with an existing investment in a plan name, we are "grandfathering" existing M+C plan names, that is, plan names established before this final rule takes effect.

Comment: One commenter believes that tax dollars should not be spent on insurance counseling and assistance programs, such as State Health Insurance Assistance (SHIP) or Information Counseling and Assistance (ICA) programs. In the commenter's view, there are less expensive and better alternatives, such as licensed insurance agents. The commenter asserted that the licensure of these individuals assures public accountability, and that the insurance professional is the best alternative for providing consumer information and expertise about the new M+C options. On the other hand, several commenters recommended that we not permit independent marketing agents to sell M+C products to potential enrollees.

Response: We believe that SHIPs and ICA programs are valuable, objective, and necessary resources for Medicare beneficiaries. These programs provide one-on-one counseling to beneficiaries on many complicated insurance issues and provide essential links to other important services and programs available to beneficiaries. SHIPs provide a service through a network of 10,000 trained volunteers. In addition, these programs effectively network with other key partners such as insurance carriers, departments of social services, and legal service agencies. SHIPs are able to provide assistance related to a broad spectrum of Medicare issues, and are required to conduct their programs with impartiality and confidentiality. While we strongly support these programs, which have been extremely valuable in educating beneficiaries on the new M+C provisions, we will continue to explore additional information mechanisms to ensure that beneficiaries receive information in the most efficient and effective manner.

We recognize that independent insurance agents may be able to provide a necessary service to Medicare beneficiaries who are considering enrolling in the M+C program. In the past, our position has been to strongly discourage, but not prohibit, Medicare managed care organizations from employing independent insurance agents to sell their products. Recently, we have engaged in extensive consultations on this issue with the DHHS Office of the Inspector General, and we intend to issue guidance to M+C organizations in the near future regarding the parameters for the participation of independent agents in marketing M+C plans.